

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION)	CASE NO. 1:17-MD-2804
)	
)	SPECIAL MASTER COHEN
THIS DOCUMENT RELATES TO:)	
“All Cases”)	
)	
)	DISCOVERY RULING NO. 14, PART 33
)	REGARDING EXPRESS SCRIPTS’
)	PRIVILEGE CLAIMS

During Track Twelve discovery, defendant Express Scripts, Inc. (ESI) invoked privilege and withheld from production certain documents—specifically, reports of ESI internal compliance audits and related records. The PEC challenged a number of these privilege designations. The parties agreed to submit a sampling of the challenged documents to the Special Master for *in camera* review, and submitted letter briefs in support of their positions.¹ Having considered these submissions carefully, the Special Master now rules as follows on the challenged documents.

I. Legal Standards.

The Special Master has applied the legal standards and authorities set out in all prior “Discovery Rulings No. 14, Part x,” and incorporates them by reference.² Because decisions regarding most of the documents at issue in this Ruling depend on the distinction between legal

¹ Letter from Anthony Irpino to Special Master (October 14, 2024); Letter from Sage R. Vanden Heuvel to Special Master (October 21, 2024).

² See, e.g., docket nos. 1321, 1353, 1359, 1380, 1387, 1395, 1498, 1593, 1610, and 1666.

and business advice, in the context of assessment of compliance with governmental regulations, the Special Master sets out those standards again here, with greater detail.³

“Ordinarily, parties may obtain discovery regarding any nonprivileged matter that is relevant to any party’s claim or defense and proportional to the needs of the case.” *Fed. Trade Comm’n v. Abbvie, Inc.*, 2015 WL 8623076 at *1 (E.D. Pa. Dec. 14, 2015). “The attorney-client privilege and work product doctrine are two exceptions to this rule.” *Id.* “The burden to establish that a privilege applies is on the party asserting the privilege.” *In re Energy Conversion Devices, Inc.*, 659 B.R. 103, 123 (Bankr. E.D. Mich. 2024); *United States v. Dakota*, 197 F.3d 821, 825 (6th Cir. 2000).

“Whether the privilege exists is a fact-intensive inquiry [that] cannot be solved by simply looking to the identity of the sender or recipient of a communication.” *BankDirect Cap. Fin., LLC v. Cap. Premium Fin., Inc.*, 326 F.R.D. 176, 180 (N.D. Ill. 2018). “Thus, it goes without saying that documents do not become cloaked with the lawyer-client privilege merely by the fact of their being passed from client to lawyer.” *Id.* Similarly, “attorney-client privilege does not shield documents merely because they were transferred to or routed through an attorney.” *Abbvie*, 2015 WL 8623076 at *3. “[T]he mere participation of a lawyer does not make statements to or from the lawyer automatically protectable. * * * Hiring lawyers to do consultants’ work does not bring a privilege into play.” *BankDirect*, 326 F.R.D. at 181.

“Because the attorney-client privilege obstructs the truth-finding process, it is construed narrowly.” *Abbvie*, 2015 WL 8623076 at *2. Specifically, the privilege is “strictly confined within the narrowest possible limits consistent with the logic of its principle.” *Id.* See also *BankDirect*, 326 F.R.D. at 181 (“Because the privilege operates in derogation of the search for truth, it is

³ To make for easier reading, all of the citations below are cleaned up and omit further reference to cases that are internally cited or quoted.

narrowly construed. It applies only where necessary to achieve its purpose.”); *In re Columbia/HCA Healthcare Corp. Billing Pracs. Litig.*, 293 F.3d 289, 294 (6th Cir. 2002) (“Claims of attorney-client privilege are narrowly construed because [the privilege] reduces the amount of information discoverable during the course of a lawsuit.”).

“Where business and legal advice are intertwined, the legal advice must predominate for the communication to be protected.” *Energy Conversion*, 659 B.R. 103 at 123; *Zigler v. Allstate Ins. Co.*, 2007 WL 1087607 at *1 (N.D. Ohio Apr. 9, 2007) (“To be privileged, the communication must have the **primary** purpose of soliciting legal, rather than business, advice.”) (emphasis in original); *Abbvie*, 2015 WL 8623076 at *3. Stated differently, “where a communication contains both legal and business advice, the attorney-client privilege will apply only if the primary purpose of the communication was to aid in the provision of legal advice.” *Id.*; see *BankDirect*, 326 F.R.D. at 181 (“Where business and legal advice are intertwined, the legal advice must predominate for the communication to be protected.”).

“[P]rivilege may . . . apply to communications between a corporation’s employees and in-house counsel, provided that the communications are made while in-house counsel is acting in his professional capacity as a lawyer.” *Rowe v. E.I. duPont de Nemours & Co.*, 2008 WL 4514092 at *7 (D.N.J. Sept. 30, 2008). “However, communications which relate to business rather than legal matters do not fall within the protection of the privilege.” *Id.*

The *Seroquel* MDL court explained why this rule must be applied especially carefully in a case where, as here, the defendant asserting privilege operates in the pharmaceutical industry:

Almost any act by a business (or an individual for that matter) carries the potential for running afoul of some law or regulation or giving rise to a civil action. The pharmaceutical industry is subject to more regulation and more complex regulation than some other industries (though less than some others). The fact of extensive or pervasive regulation does not make the everyday business activities legally privileged from discovery.

In re Seroquel Prod. Liab. Litig., 2008 WL 1995058 at *7 (M.D. Fla. May 7, 2008). The *Vioxx* MDL Court made a similar observation:

It is often difficult to apply the attorney-client privilege in the corporate context to communications between in-house corporate counsel and those who personify the corporate entity because modern corporate counsel have become involved in all facets of the enterprises for which they work. As a consequence, in-house legal counsel participates in and renders decisions about business, technical, scientific, public relations, and advertising issues, as well as purely legal issues.

In re Vioxx Prod. Liab. Litig., 501 F.Supp.2d 789, 797 (E.D. La. 2007).

Given the multiple roles played by corporate counsel, the assertion that privilege adheres to a given communication must be shown with particularity. “Determinations of privilege are generally made on a document by document basis.” *BankDirect*, 326 F.R.D. at 180. “In recognition that [i]n-house counsel performs a dual role of legal advisor and business advisor, the corporation must **clearly** demonstrate that the communication in question was made for the express purpose of securing legal not business advice.” *Abbvie*, 2015 WL 8623076 at *3 (emphasis added). Thus, “attorney-client privilege does not apply . . . if the client seeks regulatory advice for a business purpose.” *Abbvie*, 2015 WL 8623076 at *9.

As this MDL Court has observed, it is not easy to apply this test to a specific document:

While the black letter law is clear and easy to recite, it is not easy to apply in this case. The burden is on the proponent to prove that the documents are privileged; and to be privileged, the communication must have the primary purpose of soliciting or receiving legal, as opposed to business, advice. That line is sometimes very difficult to draw when . . . [a company] operates in a heavily regulated business and regulatory compliance advice from in-house counsel is therefore part of [the company’s] day-to-day business operations.

Order at 1 (docket no. 3584). *See also BankDirect*, 326 F.R.D. at 182 (acknowledging the “difficulty in negotiating the fine line between legal as opposed to business advice”).

Nonetheless, the Special Master has repeatedly ruled, and the Court has affirmed, that simple ongoing assessment of “compliance with regulations is usually a business matter, not a legal one.” *Order* at 7 (docket no. 5053); *see also Discovery Ruling No. 14-9* at 1 (docket no. 1678).

Other courts agree. *See, e.g., Ciccio v. SmileDirectClub, LLC*, 2022 WL 2182301 at *5 (M.D. Tenn June 16, 2022) (citing this MDL Court and upholding the special master’s ruling that documents were not privileged because “they involved regulatory, and not legal, advice”); *Abbvie*, 2015 WL 8623076 at *9 (“As a participant in a highly-regulated industry, a pharmaceutical company must consider regulatory matters in making nearly all of its business decisions. We note that the attorney-client privilege is construed narrowly. AbbVie has not met its burden to demonstrate that this email was sent to in-house counsel for the purpose of securing legal advice rather than business advice.”); *Rowe*, 2008 WL 4514092 at *9 (D.N.J. Sept. 30, 2008) (“The Court concludes that Exhibit 30 does not reflect the exercise of a predominantly legal function as opposed to business advice in a regulatory industry, and thus is not protected from disclosure by the attorney-client privilege.”).⁴

Finally, “[d]eterminations of the applicability of privileges to particular documents” and “decisions as to the amount of information that the District Court needs in order to make such determinations are committed to the District Judge’s discretion.” *Abbvie*, 2015 WL 8623076 at *1. “Because a special master’s ruling on the scope of permissible discovery is considered a procedural matter, the Court reviews for abuse of discretion.” *Ciccio*, 2022 WL 2182301 at *1. Thus, a district

⁴ The documents at issue in *Rowe* were from corporate counsel “advising DuPont on an ongoing regulatory dispute with the Delaware Department of Natural Resources and Environmental Control (DNREC).” *Id.* at *8.

court will uphold a special master's conclusion regarding privilege if it "is not unreasonable." *Id.* at *5.

II. The Documents

The 15 documents addressed below are all records of ESI's internal audit process, and most are preliminary or final reports of audits apparently undertaken regularly by ESI's Pharmacy Compliance Organization. Most or all of the audits were performed by a team that included ESI in-house attorney Therese Twomey, who is ESI's Senior Pharmacy Compliance Manager, and were, according to ESI's letter brief, carried out at the direction of ESI's Legal Department. Many of the documents state on their face that they were "Prepared by the Legal Department" and contain the legend "Privileged Legal Communication." (*E.g.* MDL_WITHHELD_001646.) The documents typically indicate they are reports of audits whose scope was, for example, to assess "compliance with: (1) Pharmacy Practice rules and regulations of the state of Ohio; (2) Controlled Substance regulations of Ohio; (3) Enterprise Policies; and (4) the federal Controlled Substance Act" (*E.g.* MDL_WITHHELD_001466.) Most of the documents follow a structure where the author lays out, for numerous topics, the compliance issue addressed, the regulatory or other provision controlling the issue, the findings of the audit, and a recommendation for addressing any deficiencies, if needed.

ESI argues these documents are all quintessentially legal in character and fall under attorney-client privilege. The Special Master disagrees for a number of reasons. First, as noted above, "compliance with regulations is usually a business matter, not a legal one." Docket no. 5053 at 7; DR 14-9 (docket no. 1678) at 1. Thus, although ESI's documents may well contain advice from a lawyer, the advice concerns how to structure business operations to ensure

compliance with regulatory requirements. It is business advice. It is not protected by attorney-client privilege.

The Special Master's conclusions are also supported by two other factors. First, when "in-house counsel appears as one of *many recipients* of an otherwise business-related memo, the federal courts place a heavy burden on the proponent to make a clear showing that counsel is acting in a professional legal capacity and that the document reflects legal, as opposed to business, advice." *Graff v. Haverhill N. Coke Co.*, 2012 WL 5495514 at *3-6 (S.D. Ohio Nov. 13, 2012) (emphasis added). Most of the ESI documents either bear no indication of who received them, or were sent to numerous non-lawyers. In other words, the information provided by ESI regarding each document's sender and recipient does not support a claim of privilege.

Second, a document that bears a legend marking it as privileged is not, by that fact alone, privileged; the proponent of privilege has the burden of showing "clearly" that the document contains legal advice. A party's subjective self-diagnosis that a document is privileged is not sufficient. And conclusory statements in a letter brief, or boilerplate phrases in a chart, do not carry the proponent's burden.

Accordingly, after careful review of each of the documents, as well as the parties' position statements and arguments supplied in letter briefs, the Special Master rules as follows.

MDL_WITHHELD_001433	Privilege Designation Withdrawn
MDL_WITHHELD_001434	Privilege Claim Overruled
MDL_WITHHELD_001435	Privilege Claim Overruled
MDL_WITHHELD_001466	Privilege Claim Overruled
MDL_WITHHELD_001576	Privilege Claim Overruled
MDL_WITHHELD_001646	Privilege Claim Overruled

MDL_WITHHELD_001803	Privilege Claim Overruled
MDL_WITHHELD_001834	Privilege Claim Overruled
MDL_WITHHELD_001891	Privilege Claim Overruled
MDL_WITHHELD_002843	Privilege Claim Overruled
MDL_WITHHELD_004632	Privilege Claim Overruled
MDL_WITHHELD_004827	Privilege Claim Overruled
MDL_WITHHELD_004964	Privilege Claim Overruled
MDL_WITHHELD_004965	Privilege Claim Overruled
MDL_WITHHELD_004993	Privilege Claim Overruled

III. Objections.

Any party choosing to object to any aspect of this Ruling must do so on or before
November 26, 2024.

RESPECTFULLY SUBMITTED,

/s/ David R. Cohen
David R. Cohen
Special Master

Dated: November 16, 2024